

Form PTO-1390  U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE  TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER P29215  U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/565,997
INTERNATIONAL APPLICATION NO. PCT/JP2004/011223	INTERNATIONAL FILING DATE 29 July 2004	PRIORITY DATE CLAIMED 29 July 2003
TITLE OF INVENTION RNA CAPABLE OF SUPPRESSING EXPRESSION OF KLF5 GENE		
APPLICANT(S) FOR DO/EO/US Ryozo NAGAI, Ichiro MANABE, Atsushi ISHIHARA, Tsuneaki TOTTORI		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information.		
<ol style="list-style-type: none"> <li>1. <input type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.</li> <li>2. <input checked="" type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.</li> <li>3. <input type="checkbox"/> This is an express request to promptly begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (23) indicated below.</li> <li>4. <input type="checkbox"/> The US has been elected (PCT Article 31).</li> <li>5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))             <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> has been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</li> </ol> </li> <li>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371 (c)(2)).             <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto.</li> <li>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154 (d) (4).</li> </ol> </li> <li>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))             <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> have been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li>d. <input type="checkbox"/> have not been made and will not be made.</li> </ol> </li> <li>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</li> <li>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).                  "Executed"</li> <li>10. <input type="checkbox"/> An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</li> </ol>		
<b>Items 11 to 22 below concern other document(s) or information included:</b>		
11. Assignee: <u>KYOWA HAKKO KOGYO CO., LTD., of Tokyo, Japan; Ryozo NAGAI, of Tokyo, Japan; and Ichiro MANABE, of Tokyo, Japan</u>		
12. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.		
13. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.		
14. <input checked="" type="checkbox"/> A FIRST preliminary amendment. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment.		
15. <input type="checkbox"/> An Application Data Sheet under 37 C.F.R. 1.76.		
16. <input type="checkbox"/> A substitute specification.		
17. <input type="checkbox"/> A power of attorney and/or change of address letter.		
18. <input type="checkbox"/> Figure of Drawing to be published:		
19. <input checked="" type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825.		
20. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154 (d) (4).		
21. <input type="checkbox"/> A second copy of the English language translation of the international of the international application under 35 U.S.C. 154 (d) (4).		
22. <input checked="" type="checkbox"/> Other items or information: Cover Letter. Statement to Support Filing and Submission in Accordance with 37 C.F.R. §1.821-1.825. Paper copy of sequence listing.		

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)		INTERNATIONAL APPLICATION NO.		ATTORNEY'S DOCKET NUMBER	
10/565,997		PCT/JP2004/011223		P29215	
23 <input type="checkbox"/> The following fees are submitted: Basic national fee..... <b>300.00</b>				CALCULATIONS	PTO USE ONLY
				\$ 0.00	
24 <input type="checkbox"/> Examination Fee If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33 (1)-(4)..... <b>100.00</b> All other situations..... <b>200.00</b>				\$ 0.00	
25 <input type="checkbox"/> Search fee Search fee (37 CFR 1.445(a) (2)) has been paid on the international application to the USPTO as an International Searching Authority..... <b>100.00</b> International Search Report prepared and provided to the Office..... <b>400.00</b> All other situations..... <b>500.00</b>				\$ 0.00	
<b>TOTAL 23, 24 and 25 =</b>				\$ 0.00	
<input type="checkbox"/> Additional Fee for Specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in electronic medium). The fee is \$250.00 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
-100=	/50 =		x \$250.00	\$ 0.00	
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(h)).				\$130.00	
Claims	Number Filed	Number Extra	Rate		
Total Claims	18 - 20 =	0	x \$50.00	\$ 0.00	
Independent Claims	2 - 3 =	0	x \$200.00	\$ 0.00	
Multiple Dependent Claim(s) (if applicable)			+ \$360.00	\$ 0.00	
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$130.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$ 0.00	
<b>SUBTOTAL =</b>				\$130.00	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492 (i)).				\$ 0.00	
Extension of Time fee in the amount of \$				\$ 0.00	
<b>TOTAL NATIONAL FEE =</b>				\$130.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				\$ 0.00	
<b>TOTAL FEES ENCLOSED =</b>				\$130.00	
				Amount to be refunded	\$
				Charged	\$
a. <input checked="" type="checkbox"/> A check in the amount of <u>\$130.00</u> to cover the above fees is included. b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. c. <input checked="" type="checkbox"/> The U.S. Patent and Trademark Office is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>19-0089</u> . d. <input type="checkbox"/> Fees are to be charged to a credit card. <b>WARNING:</b> Information on this form may become public. <b>Credit card information should not be included on this form.</b> Provide credit card information and authorization on PTO-2038. <b>NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.</b>					
SEND ALL CORRESPONDENCE TO CUSTOMER NO. 07055 AT THE PRESENT ADDRESS OF:					
Bruce H. Bernstein GREENBLUM & BERNSTEIN, P.L.C. 1950 Roland Clark Place Reston, VA 20191 (703) 716-1191					
SIGNATURE <i>Sean Myers Rague</i> Bruce H. Bernstein NAME 29,027 REGISTRATION NUMBER <b>42,920</b>					

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Ryozo NAGAI et al. **Mail Stop PCT**  
Appl. No. : 10/565,997 (National Stage of PCT/JP2004/011223)  
I. A. Filed : July 29, 2004  
For : RNA CAPABLE OF SUPPRESSING EXPRESSION OF KLF5 GENE

**COVER LETTER**

**Mail Stop PCT**

Commissioner for Patents  
U.S. Patent and Trademark Office  
Customer Service Window, Mail Stop PCT  
Randolph Building  
401 Dulany Street  
Alexandria, VA 22314

Sir:

In order to comply with the requirements (copy enclosed) for the submission of an executed Declaration of the International Application set forth in the Notification mailed June 12, 2006 which sets a two-month period of response until August 14, 2006 (being that August 12, 2006 falls on a Saturday), Applicants hereby submit:

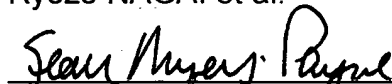
- Transmittal Letter to the United States Designated/Elected Office Concerning a Filing Under 35 U.S.C. 371;
- an executed Declaration and Power of Attorney;
- a Statement to Support Filing and Submission in Accordance with 37 C.F.R. §1.821-1.825;
- a Diskette containing sequence listing, together with paper copy/written of the same (20 pages);

- a Preliminary Amendment;
- an Information Disclosure Statement, form PTO-1449, and references cited; and
- a check in the amount of \$130.00 as payment of the surcharge for late filing of the Declaration.

The U.S. Patent and Trademark Office is hereby authorized to charge any additional fees or credit any overpayment to Deposit Account No. 19-0089.

Should the Examiner have any questions, he is invited to contact the undersigned at the below-listed number.

Respectfully submitted,  
Ryozo NAGAI et al.

  
\_\_\_\_\_  
Bruce H. Bernstein  
Reg. No. 29,027 42,920

August 14, 2006  
GREENBLUM & BERNSTEIN, P.L.C.  
1950 Roland Clarke Place  
Reston, VA 20191  
(703) 716-1191



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/565,997	Ryozo Nagai	P29215

INTERNATIONAL APPLICATION NO.
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PCT/JP04/11223

I.A. FILING DATE	PRIORITY DATE
07/29/2004	07/29/2003

07055  
 GREENBLUM & BERNSTEIN, P.L.C.  
 1950 ROLAND CLARKE PLACE  
 RESTON, VA 20191

CONFIRMATION NO. 9551

371 FORMALITIES LETTER



\*OC000000019208074\*

Date Mailed: 06/12/2006

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 01/27/2006
- English Translation of the IA filed on 01/27/2006
- Copy of the International Search Report filed on 01/27/2006
- Preliminary Amendments filed on 01/27/2006
- Oath or Declaration filed on 01/27/2006
- Request for Immediate Examination filed on 01/27/2006
- U.S. Basic National Fees filed on 01/27/2006
- Priority Documents filed on 01/27/2006

**RECEIVED**

JUN 14 2006

GREENBLUM &amp; BERNSTEIN PLC

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date. The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) in that it:
  - is not executed in accordance with either 37 CFR 1.66 or 37 CFR 1.68.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

## SUMMARY OF FEES DUE:

Total additional fees required for this application is \$130 for a Large Entity:

- **\$130 Surcharge.**

- This application clearly fails to comply with the requirements of 37 CFR. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing", an initial paper or compact disc copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application.** Applicant must also provide a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.
- A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ [ebc@uspto.gov](mailto:ebc@uspto.gov)

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

LAMONT M HUNTER

Telephone: (703) 308-9140 EXT 201

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.

10/565,997

INTERNATIONAL APPLICATION NO.

PCT/JP04/11223

ATTY. DOCKET NO.

P29215

FORM PCT/DO/EO/905 (371 Formalities Notice)